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Search Results - Record(s) 1 through 1 of 1 returned.

☑ 1. Document ID: US 5663415 A

L21: Entry 1 of 1 File: USPT Sep 2, 1997

US-PAT-NO: 5663415
DOCUMENT-IDENTIFIER: US 5663415 A

TITLE: Process for preparing antihistamine tannates

DATE-ISSUED: September 2, 1997

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Chopdekar; Vilas M.	Edison	NJ		
Schleck; James R.	Somerset	NJ		
Brown; Vernon A.	Maplewood	NJ		
Guo; Cheng	Harrison	NJ		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Jame Fine Chemicals, Inc.	Bound Brook	NJ			02

APPL-NO: 08/ 671604 [PALM]
DATE FILED: June 28, 1996

INT-CL: [06] C07 C 69/88

US-CL-ISSUED: 560/68
US-CL-CURRENT: 560/68

FIELD-OF-SEARCH: 560/68

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
5599846	February 1997	Chopdekar	514/653

FOREIGN PATENT DOCUMENTS

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FOREIGN-PAT-NO	PUBN-DATE	COUNTRY	US-CL
239327	September 1996	JP	

ART-UNIT: 124

PRIMARY-EXAMINER: Nazario-Gonzalez; Porfirio

ABSTRACT:

A process for preparing pure antihistamine tannate compositions. The antihistamine in the form of its free base is contacted with tannic acid in the presence of water for a period of time of about 5 minutes to 4 hours and at a maximum temperature such that not more than about 5 wt. % of the antihistamine tannate will be decomposed. Water is removed from the antihistamine tannate by freeze-drying.

10 Claims, 0 Drawing figures
Exemplary Claim Number: 1

BRIEF SUMMARY:

1 FIELD OF THE INVENTION

2 The invention relates to a process for preparing antihistamine tannate compositions having a high level of purity, e.g. at least 90 wt. %, based on the weight of the composition, with the balance comprising primarily water.

3 BACKGROUND OF THE INVENTION

4 Antihistamine compounds in the form of their free bases as well as their salts, e.g. hydrochloride, maleate, tannate, etc. are well known. Frequently, it is desirable to utilize the antihistamine in the form of its tannate salt, because such salt is generally quite stable and may be administered in such form without any untoward side effects. Tannic acid, also known as tannin, is a well known naturally occurring substance. Commercially available tannic acid usually contains about 5 wt. % water, has a molecular weight of about 1700 and is typically produced from Turkish or Chinese nutgall.

5 Commercially available antihistamine tannate compositions are relatively impure. Such compositions are typically prepared by reacting the antihistamine free base with tannic acid in the presence of a volatile solvent, usually isopropanol. The yield is only fair (e.g. about 70%) and decomposition products e.g. 2-5 wt. %, and a significant amount of the volatile solvent, e.g. 6-10 wt. %, based on the weight of the composition, remains with the product and cannot be removed.

6 Typically, in the conventional isopropanol route, the antihistamine free base and the tannic acid will be present in the isopropanol at a concentration of about 20 wt. %, based on the weight of the reaction mixture. The reaction mixture is stirred for about one hour, while maintaining a temperature of 60.degree.-70.degree. C. The reaction mixture is cooled to room temperature and filtered. The precipitate is vacuum dried for an extended period of time at a temperature of 60.degree.-80.degree. C. A yield of product of only about 70% is obtained and the product purity will be about 85-90 wt. %, based on the

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weight of the composition (the impurities consist of isopropanol and decomposition products which cannot be removed).

7 Many antihistamine tannates, e.g. phenylephrine tannate, are heat sensitive and therefore undergo decomposition quite readily upon prolonged exposures to temperatures as low as 50.degree. C. Accordingly, even when the solvent utilized in its preparation has a relatively high vapor pressure such as is in the case of isopropanol, it is impossible to reduce the solvent content below about 6 wt. %, based on the weight of the antihistamine tannate composition, even at reduced pressures and very mild elevated temperatures. Moreover, from an environmental point, it would be most desirable if the antihistamine tannate could be prepared such that the use of volatile solvents could be avoided.

8 SUMMARY OF INVENTION

9 It has now been found that it is possible to prepare pure antihistamine tannate compositions by a synthetic route which results in the production of compositions having a minimum purity level of at least 90 wt. %, usually at least 95 wt. % and often at least 98 wt. %, based on the weight of the composition, with a yield of at least about 90% and often with a yield in excess of 97%. The chief "impurity" present in the compositions prepared by the process of the invention is water which is present in an amount of 1-5 wt. %, based on the weight of the composition. Indeed, it has been found possible to produce antihistamine tannate compositions having a purity level of at least 99 wt. % and a water content of less than 1 wt. %, based on the weight of the composition.

10 Since the pure antihistamine tannate compositions prepared by the process of the invention is administered either in solid form, i.e. a pill, or as a suspension, the minimal amount of water present in the composition cannot be considered to be an impurity of the nature associated with degradation products or volatile organic compounds such as isopropanol. The dosage to be administered can be readily adjusted by taking into account the insignificant amount of water present in the composition.

11 DETAILS OF THE INVENTION

12 The process of the invention comprises the following steps:

13 (a) contacting an antihistamine in the form of its free base with tannic acid in the presence of water at a maximum temperature which will not cause decomposition of the antihistamine tannate to an extent of greater than about 5 wt %, based on the weight of the antihistamine tannate;

14 (b) allowing the antihistamine to remain in contact with the tannic acid in the presence of water for a period of time in the range of about 5 minutes to 4 hours, preferably 15 minutes to 2 hours, at said maximum temperature; and

15 (c) freeze-drying the antihistamine tannate resulting from step (b) at a temperature and at a reduced pressure and for such period of time that (i) at least about 90 wt. % of the water is removed from the antihistamine tannate and (ii) decomposition of the antihistamine tannate will be limited to a maximum of about 5 wt. %.

16 In the event that the antihistamine is present as the salt, e.g. the hydrochloride, it is dissolved in cold water and neutralized with a

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stoichiometric amount of a base such as sodium or potassium hydroxide. The antihistamine free base precipitates out, recovered by filtration, washed with cold water until all chloride salts have been removed, and air dried at ambient temperatures.

17 The molar ratio of antihistamine free base to tannic acid will generally be in the range of about 4:1 to 6:1, but is preferably stoichiometric, i.e. 5:1, although such ratio may vary somewhat since tannic acid is a complex substance which varies from batch to batch. The exact molar ratio to be used for a given batch of tannic acid may be readily determined by one skilled in the art by preparing small aliquot samples having variations within the 4:1 to 6:1 molar ratio and determining the exact molar ratio to be used after working up the product such that neither excess antihistamine free base nor excess tannic acid will be present in the final product.

18 The maximum temperature of the reaction mixture (anti-histamine free base, tannic acid and water) will vary depending on the particular antihistamine and its heat sensitivity. Best results will be achieved by conducting the reaction at ambient temperatures, e.g. 20.degree.-30.degree. C.; if the reaction between the desired antihistamine free base and the tannic acid is unduly slow, the temperature may be elevated to a maximum of that which will not cause any significant degradation (e.g. less than about 5 wt. %) of the antihistamine tannate.

19 The antihistamine to be reacted with the tannic acid is selected from the group consisting of phenylephrine, carbetapentane, pyrilamine, chlorpheniramine, ephedrine, pseudoephedrine, brompheniramine, bromodiphenhydramine, diphenhydramine, pheniramine, phenyltoxamine, clemastine, tripelennamine, cyproheptadine, phenindamine and phenyltoloxamine. Phenylephrine tannate is a heat-sensitive compound, and, as such, will benefit from its preparation by the process of the invention.

20 The water is removed from the reaction mixture by freeze-drying, a well known technique for removing water from compositions. Although freeze-drying to remove the water is a time-consuming process (one liter of reaction mixture containing one liter of water will typically take 30-36 hours to remove about 97 wt. % of the water present in the reaction mixture), it has been found to be the only method for removing water from heat-sensitive antihistamine tannate compositions without any significant formation of decomposition products. While volatile organic solvents such as isopropanol may be more quickly removed by evaporation at reduced pressures and elevated temperatures, there will always be impurities, i.e. isopropanol and decomposition products, in the product which cannot be removed without further degradation of the product. Moreover, the process of the invention will result in a yield of at least about 90%, versus the typical yield of about 70% obtained from the isopropanol route.

21 The freeze-drying of the reaction mixture resulting from step (b) will typically be carried out at a reduced pressure and reduced temperature, e.g. a pressure of not greater than about 500 milliTorre, preferably 300 to 100 milliTorre and at a temperature in the range of about -60.degree. C. to -20.degree. C., preferably -50.degree. to -40.degree. C. The desired end point of the freeze-drying process may be determined by condensing and measuring the quantity of water vapor removed during the freeze-drying process. The time required for completion of the freeze-drying process will vary depending on factors such as pressure, temperature, quantity to be freeze-dried, desired level of water to be tolerated in the final product, the thickness and surface area of the reaction mixture layers in the trays of the freeze-drying equipment, etc.

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22 Steps (a) and (b) may be effected my any type of desired mixing, such as conventional stirrers. Upon allowing the reaction mixture resulting from step (b) to stand, it will be noticed that two layers will form. To insure that as much antihistamine tannate product as possible is recovered, it is preferred that the entire mass of reaction mixture resulting from step (b) be subjected to freeze-drying.

DETAILED DESCRIPTION:

1 The following nonlimiting examples will serve to illustrate the present invention. These examples were carried out using phenylephrine free base as the antihistamine. Phenylephrine is a histamine which is frequently administered in the form of its tannate and it is quite heat-sensitive, i.e. prolonged exposures to temperatures as low as 50.degree. C. will cause significant decomposition of the product. Phenylephrine as the free base has a melting point of 169.degree.-172.degree. C. and may be prepared from m-hydroxy-.omega.-chloroacetophenone and methyl-amine, see U.S. Pat. Nos. 1,932,947 and 1,954,389.

2 EXAMPLE 1

3 (Comparative Example)

4 In this example, phenylephrine tannate was synthesized by the isopropanol route for comparative purposes. A reaction vessel consisting of a 2-liter, 3-neck flask was set up with a thermometer, stirrer, condenser and heating mantle. 20 g phenylephrine free base and 400 g isopropanol were added to the flask and the contents were heated, with stirring, to 65.degree.-70.degree. C. in order to dissolve the phenylephrine base. A separate solution of 43.2 g of tannic acid (mol. wt. of about 1700) in 400 g isopropanol was prepared and heated to 40.degree. C., with stirring.

5 The tannic acid solution was slowly added, with stirring, to the reaction vessel over a period of about 30 minutes, while maintaining the contents of the reaction vessel at a temperature of about 70.degree. C. The reaction mixture was stirred for about 60 minutes, while maintaining a temperature of about 70.degree. C. and was thereafter cooled to about 15.degree. C. The phenylephrine tannate product was recovered from the reaction mixture by filtration and was then washed with 50 g of isopropanol.

6 The phenylephrine product was then vacuum dried at about 1 mm Hg pressure and at about 60.degree. C. temperature over a period of about 60 minutes. The yield of product was 45.5 g (72% yield) and its density was 0.45 g/cc. GC and HPLC analysis indicated that the product contained about 8 wt. % isopropanol and about 2 wt. % of degradation products. All efforts to remove the isopropanol and degradation products by further prolonged vacuum drying failed.

7 EXAMPLE 2

8 Phenylephrine tannate was synthesized by the process of the invention as follows. In a 5-liter flask were placed 680 g tannic acid (mol. wt. of about 1700) in 1 kg water. The temperature of the solution was ambient (about 22.degree. C.) and, while stirring, 320 g phenylephrine free base were added

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to the flask over a 15-minute period. Stirring was continued for an additional 2 hours. Upon allowing the reaction mixture to stand, it was noted that two layers had formed.

9 The entire mass of the reaction mixture was then freeze-dried at a reduced pressure of 200-100 milliTorre and a temperature of -50.degree. to -40.degree. C. for about 36 hours. At this point, the water which had been removed was condensed and its weight equalled about 1 kg. The dried phenylephrine base was found to contain 2 wt. % of water and it had a density of 0.8 g/cc. Analysis of the product by HPLC showed no discernible amounts of materials other than phenylephrine tannate and water. The overall yield of product was 96%.

CLAIMS:

What is claimed is:

1. A process for preparing an antihistamine tannate composition which comprises the steps of:

(a) contacting an antihistamine in the form of its free base with tannic acid in the presence of water at a maximum temperature which will not cause decomposition of the antihistamine tannate to an extent of greater than about 5 wt %, based on the weight of the antihistamine tannate;

(b) allowing the antihistamine to remain in contact with the tannic acid in the presence of water for a period of time in the range of about 5 minutes to 4 hours at said maximum temperature; and

(c) freeze-drying the antihistamine tannate resulting from step (b) at a temperature and at a reduced pressure and for such period of time that (i) at least about 90 wt. % of the water is removed from the antihistamine tannate and (ii) decomposition of the antihistamine tannate will be limited to a maximum of about 5 wt. %.

2. The process of claim 1 wherein the antihistamine is selected from the group consisting of phenylephrine, carbetapentane, pyrilamine, chlorpheniramine, ephedrine, pseudoephedrine, brompheniramine, bromodiphenhydramine, diphenhydramine, pheniramine, phenyltoxamine, clemastine, tripelennamine, cyproheptadine, phenindamine and phenyltoloxamine.

3. The process of claim 2 wherein the antihistamine comprises phenylephrine.

4. The process of claim 1 wherein the molar ratio of the tannic acid to the antihistamine is in the range of about 4:1 to 6:1.

5. The process of claim 1 wherein the water is present in an amount such that the weight ratio of tannic acid to water is in the range of 1:10 to 10:1.

6. The process of claim 1 wherein the contact time in step (b) is in the range of 15 minutes to 2 hours.

7. The process of claim 1 wherein the freeze-drying is carried out at a pressure of not greater than about 500 milliTorre and at a temperature in the range of about -60.degree. C. to -20.degree. C.

8. The process of claim 7 wherein the freeze-drying is carried out at a

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pressure in the range of 300 to 100 milliTorre and a temperature in the range of -50.degree. to -40.degree. C.

9. The process of claim 1 wherein the entire mass of the reaction mixture resulting from step (b) is subjected to freeze-drying.

10. The process of claim 1 wherein steps (a) and (b) are carried out at temperatures in the range of about 20.degree.-30.degree. C.

Terms	Documents
5663415.pn.	1

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Set Name side by side	Query	Hit Count	Set Name result set
	DB=USPT,PGPB,JPAB,EPAB,DWPI; PLUR=YES; OP=OR		
L33	(phenylephrine near tannate) same guanifenesin	0	L33
L32	(carbetapentane adj3 (tannic or tannate))	10	L32
L31	(carbetapentane near (tannic or tannate))	7	L31
L30	l11 and (tannic or tannate)	5	L30
L29	l11 and tannate	2	L29
L28	L27 and tannate	21	L28
L27	l23 and guaifenesin	125	L27
L26	l23 and guanefensin	0	L26
L25	l22 and (carbetapentane near tannate)	0	L25
L24	L23 and (carbetapentane near tannate)	0	L24
L23	(antitussive) same expectorant	693	L23
L22	(antitussive) and expectorant	811	L22
L21	(anti near tussive) same expectorant same combination	3	L21
L20	(anti near tussive) same expectorant same combination	3	L20
L19	L18 and (carbetapentane near tannate)	0	L19
L18	(anti near tussive) and expectorant	129	L18
L17	L15 and (guaifenesin)	24	L17
L16	L15 and (carbetapentane near tannate)	0	L16
L15	(anti near tussive) same expectorant	111	L15
L14	(anti near tissusive) same expectorant	0	L14
L13	guaifenesin and (carbetapentane same tannate)	0	L13
L12	guaifenesin same carbetapentane	28	L12
L11	guaifenesin and carbetapentane	105	L11
L10	L9 same guaifenesin	63	L10
L9	phenylephrine same expectorant	110	L9
L8	guaifenesin same (tannate)	11	L8
L7	guaifenesin and (tannate)	23	L7
L6	(carbetapentane near tannate)	7	L6
L5	L4 and (respiratory or asthma or cough)	215	L5
L4	l1 and oral	323	L4
L3	l1 and oral	323	L3
L2	guaifenesin and (carbetapentane near tannate)	0	L2
L1	guaifenesin or (carbetapentane near tannate)	446	L1

END OF SEARCH HISTORY

updated 1/5/04

updated 1/28/03

=> D L16 IALL 3

L16 ANSWER 3 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 1999:4643 DRUGLAUNCH
SOURCE: Drug Launches, (17 May 1999)
DOCUMENT NUMBER: 0182701
TRADE NAME: TRIPLE TANNATE
MANUFACTURER: Mova
CORPORATION: Mova
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Dec 1998
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: chlorphenamine **tannate**, 2 mg/5 ml, **phenylephrine tannate**, 5 mg/5 ml, mepyramine tannate, 12.5 mg/5 ml.

NO. OF INGREDIENTS: 3
INDICATIONS: **Nasal** congestion
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral 480 ml 1

Searched by John Dantzman 308-4488

=> D L16 IALL 4

L16 ANSWER 4 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 1999:1121 DRUGLAUNCH
SOURCE: Drug Launches, (22 Mar 1999)
DOCUMENT NUMBER: 0179128
TRADE NAME: TUSSI-12
MANUFACTURER: Wallace
CORPORATION: Carter-Wallace
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Dec 1998
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: pentoxyverine tannate, 30 mg, chlorphenamine **tannate**, 4 mg, **phenylephrine tannate**, 5 mg.

NO. OF INGREDIENTS: 3
INDICATIONS: Common **cold, nasal** congestion
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral 480 ml 1

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L16 ANSWER 5 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 1998:13675 DRUGLAUNCH
SOURCE: Drug Launches, (21 Dec 1998)
DOCUMENT NUMBER: 0176901
TRADE NAME: TUSSI-12
MANUFACTURER: Wallace
CORPORATION: Carter-Wallace
LAUNCH COUNTRY: United States
LAUNCH DATE: Nov 1998
CLASSIFICATION: R5D Cough Sedatives
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: pentoxyverine tannate, 30 mg, chlorphenamine tannate, 4 mg, phenylephrine tannate, 5 mg.
Excipient: benzoic acid; FD&C blue 1; FD&C red 3; FD&C red 40; FD&C yellow 5; flavor; glycerol; kaolin; magnesium aluminium silicate; methylparaben; pectin; purified water; saccharin sodium; sucrose.
NO. OF INGREDIENTS: 3
INDICATIONS: Cough associated with colds, bronchial asthma, acute and chronic bronchitis
DOSE FORM: suspension oral
PACKAGE/PRICE: suspension oral 487 ml

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L16 ANSWER 6 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 1998:9058 DRUGLAUNCH
SOURCE: Drug Launches, (17 Aug 1998)
DOCUMENT NUMBER: 0172212
TRADE NAME: R-TANNATE
MANUFACTURER: Discount Generics
CORPORATION: Discount Generics
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Apr 1998
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: **suspension** oral (paed): chlorphenamine **tannate**, 2 mg/5 ml, **phenylephrine tannate**, 5 mg/5 ml, mepyramine tannate, 12.5 mg/5 ml; tabs: chlorphenamine **tannate**, 8 mg, **phenylephrine tannate**, 25 mg, mepyramine **tannate**, 25 mg.

NO. OF INGREDIENTS: 3
INDICATIONS: **Nasal** congestion, **rhinitis**
DOSE FORM: **suspension** oral; tabs
PACKAGE/PRICE: **suspension** oral (paed) 120 ml 1; tabs 100

=> D L16 IALL 7

L16 ANSWER 7 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 1998:371 DRUGLAUNCH
SOURCE: Drug Launches, (19 Jan 1998)
DOCUMENT NUMBER: 0163340
TRADE NAME: TRIPLE TANNATE
MANUFACTURER: Grove
CORPORATION: Grove
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Sep 1997
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: chlorphenamine **tannate**, 2 mg/5 ml, **phenylephrine** tannnate, 5 mg/5 ml, mepyramine tannate, 12.50 mg/5 ml.

NO. OF INGREDIENTS: 3
INDICATIONS: **Nasal** congestion
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral (paed) 120 ml 1

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L16 ANSWER 8 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 97:5170 DRUGLAUNCH
SOURCE: Drug Launches, (19 May 1997)
DOCUMENT NUMBER: 0154800
TRADE NAME: ATROHIST
MANUFACTURER: Medeva Pharm
CORPORATION: Medeva (UK)
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Mar 1997
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: **suspension** oral a (paed): **phenylephrine tannate**, 5 mg/5 ml, chlorphenamine tannate, 2 mg/5 m, mepyramine tannate, 12.5 mg/5 ml; **suspension** oral b (paed): **phenylephrine tannate**, 5 mg/5 ml, chlorphenamine tannate, 2 mg/5 m, mepyramine tannate, 12.5 mg/5 ml.

NO. OF INGREDIENTS: 3
INDICATIONS: Systemic **nasal** preparation
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral a (paed) 120ml 1; **suspension** oral b (paed) 480 ml 1

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L16 ANSWER 9 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 97:4831 DRUGLAUNCH
SOURCE: Drug Launches, (19 May 1997)
DOCUMENT NUMBER: 0154455
TRADE NAME: GELHIST
MANUFACTURER: Econolab
CORPORATION: Econolab
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Jan 1997
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: chlorphenamine **tannate**, 2 mg/5 ml, **phenylephrine**, 5 mg/5 ml, mepyramine, 12.5 mg/5 ml.
NO. OF INGREDIENTS: 3
INDICATIONS: Allergic **rhinitis**
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral (paed) 480 ml 1

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L16 ANSWER 10 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 97:234 DRUGLAUNCH
SOURCE: Drug Launches, (20 Jan 1997)
DOCUMENT NUMBER: 0149758
TRADE NAME: PHENATAN-S
MANUFACTURER: Mova
CORPORATION: Mova
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Sep 1996
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: chlorphenamine **tannate**, 2 mg, **phenylephrine tannate**, 5 mg, mepyramine **tannate**, 12.5 mg.
NO. OF INGREDIENTS: 3
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral 118 ml 1

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L16 ANSWER 11 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 95:12027 DRUGLAUNCH
SOURCE: Drug Launches, (18 Dec 1995)
DOCUMENT NUMBER: 0136052
TRADE NAME: TRIOTANN
MANUFACTURER: Discount Generics
CORPORATION: Discount Generics
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Sep 1995
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: **suspension** oral: **phenylephrine tannate**, 5 mg/5 ml, chlorphenamine tannate, 2 mg/5 ml, mepyramine tannate, 12.5 mg/5 ml; tabs: **phenylephrine tannate**, 25 mg, chlorphenamine **tannate**, 8 mg, mepyramine tannate, 25 mg.
NO. OF INGREDIENTS: 3
INDICATIONS: Systemic **nasal** preparation
DOSE FORM: **suspension** oral; tabs
PACKAGE/PRICE: **suspension** oral 120 ml 1; tabs 100

=> D L16 IALL 12

L16 ANSWER 12 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 95:5612 DRUGLAUNCH
SOURCE: Drug Launches, (19 Jun 1995)
DOCUMENT NUMBER: 0129566
TRADE NAME: TRI-TANNATE
MANUFACTURER: Geneva Generics
CORPORATION: Ciba-Geigy
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Dec 1994
CLASSIFICATION: R5A **Cold** Preparations without Anti-infectives
COMPOSITION: Active Ingredient: **phenylephrine** tannate , 5 mg/5 ml, chlorphenamine tannate, 2 mg/5 ml, pyrilamine tannate, 12.5 mg/5 ml.
NO. OF INGREDIENTS: 3
INDICATIONS: Treatment of **cold**
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral (paed) 480 ml 1

Searched by John Dantzman 308-4488

=> D L16 IALL 13

L16 ANSWER 13 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 95:5610 DRUGLAUNCH
SOURCE: Drug Launches, (19 Jun 1995)
DOCUMENT NUMBER: 0129564
TRADE NAME: RICOBIN-D
MANUFACTURER: Alba
CORPORATION: Alba Pharm
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Dec 1994
CLASSIFICATION: R1B Systemic **Rhinologicals**
COMPOSITION: Active Ingredient: **phenylephrine tannate**, 5 mg/5 ml.
NO. OF INGREDIENTS: 1
INDICATIONS: Systemic **nasal** preparation
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral 120 ml 1

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L16 ANSWER 14 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 95:5609 DRUGLAUNCH
SOURCE: Drug Launches, (19 Jun 1995)
DOCUMENT NUMBER: 0129563
TRADE NAME: RICOBID
MANUFACTURER: Alba
CORPORATION: Alba Pharm
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Dec 1994
CLASSIFICATION: R1B Systemic **Rhinologicals**
COMPOSITION: Active Ingredient: chlorphenamine **tannate**, 4 mg/5 ml, **phenylephrine tannate**, 5 mg/5 ml.
NO. OF INGREDIENTS: 2
INDICATIONS: Systemic **nasal** preparation
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral (paed) 120 ml 1

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L16 ANSWER 15 OF 15 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 95:3515 DRUGLAUNCH
SOURCE: Drug Launches, (17 Apr 1995)
DOCUMENT NUMBER: 0127440
TRADE NAME: QUAD-TUSS TANNATE
MANUFACTURER: Hitech
CORPORATION: Hitech
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Jan 1995
CLASSIFICATION: R1B Systemic **Rhinologicals**
COMPOSITION: Active Ingredient: **phenylephrine tannate**, 5 mg/5 ml, chlorphenamine tannate, 2 mg/5 ml, pyrilamine tannate, 12.5 mg/5 ml.
NO. OF INGREDIENTS: 3
INDICATIONS: Systemic **nasal** preparation
DOSE FORM: **suspension** oral
PACKAGE/PRICE: **suspension** oral (paed) 480 ml 1

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L17 ANSWER 3 OF 11 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 1999:1114 DRUGLAUNCH
SOURCE: Drug Launches, (22 Mar 1999)
DOCUMENT NUMBER: 0179121
TRADE NAME: TRI-TANNATE
MANUFACTURER: Amide
CORPORATION: Amide
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: Dec 1998
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: **phenylephrine tannate**, 25 mg, chlorphenamine **tannate**, 8 mg, mepyramine tannate, 25 mg.
NO. OF INGREDIENTS: 3
INDICATIONS: Common **cold, nasal** congestion
DOSE FORM: tabs
PACKAGE/PRICE: tabs 100

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L17 ANSWER 4 OF 11 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 96:8745 DRUGLAUNCH
SOURCE: Drug Launches, (23 Sep 1996)
DOCUMENT NUMBER: 0144945
TRADE NAME: TRITAN
MANUFACTURER: Eon
CORPORATION: Eon
LAUNCH COUNTRY: Puerto Rico
LAUNCH DATE: May 1996
CLASSIFICATION: R1B Systemic **Rhinologicals**
FILE SEGMENT: Product Listing
COMPOSITION: Active Ingredient: **phenylephrine tannate**
, 25 mg, chlorphenamine **tannate**
, 8 mg, mepyramine tannate, 25 mg.
NO. OF INGREDIENTS: 3
INDICATIONS: Preparado **nasal** sistemico
DOSE FORM: tabs
PACKAGE/PRICE: tabs 10

=> D IALL 5

L17 ANSWER 5 OF 11 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 94:57066 DRUGLAUNCH
SOURCE: Drug Launches, (22 Nov 1993)
DOCUMENT NUMBER: 0110372
TRADE NAME: TRI-NATAN
MANUFACTURER: Gianfarma
CORPORATION: Gianfarma
LAUNCH COUNTRY: Peru
LAUNCH DATE: Aug 1993
CLASSIFICATION: R1B Systemic **Rhinologicals**
COMPOSITION: Active Ingredient: oral susp: **phenylephrine tannate**, 5 mg/5 ml, chlorphenamine tannate, 2 mg/5 ml, mepyramine tannate, 12.5 mg/5 ml; tabs: **phenylephrine tannate**, 25 mg, chlorphenamine **tannate**, 8 mg, mepyramine tannate, 25 mg.
NO. OF INGREDIENTS: 3
INDICATIONS: **Sinusitis** catarral, rinitis aguda, reacciones medicamentosas
DOSE FORM: oral susp; tabs
PACKAGE/PRICE: oral susp 60 ml 1 Sol 3.31 (RPP); tabs 30 Sol 6.56 (RPP)

=> D IALL 6

L17 ANSWER 6 OF 11 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 94:56857 DRUGLAUNCH
SOURCE: Drug Launches, (22 Nov 1993)
DOCUMENT NUMBER: 0110158
TRADE NAME: R-TANNATE
MANUFACTURER: Aligen Independent
CORPORATION: Aligen
LAUNCH COUNTRY: United States
LAUNCH DATE: Aug 1993
CLASSIFICATION: R1B Systemic Rhinologicals
COMPOSITION: Active Ingredient: phenylephrine tannate , 5 mg, chlorphenamine tannate , 2 mg, pyrilamine tannate, 12.5 mg.
NO. OF INGREDIENTS: 3
INDICATIONS: Decongestant and antihistamine
DOSE FORM: oral susp
PACKAGE/PRICE: oral susp 480 ml 1 US$ 21.45 (RPP)

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L17 ANSWER 7 OF 11 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 94:49121 DRUGLAUNCH
SOURCE: Drug Launches, (22 Mar 1993)
DOCUMENT NUMBER: 0049139
TRADE NAME: TRIN-TUSS
MANUFACTURER: Trinity Tech
CORPORATION: Trinity Tech
LAUNCH COUNTRY: United States
LAUNCH DATE: Dec 1992
CLASSIFICATION: R5A **Cold** Preparations without Anti-infectives
COMPOSITION: Active Ingredient: **phenylephrine tannate**, 10 mg, ephedrine **tannate**, 10 mg, chlorphenamine **tannate**, 5 mg, **carbetapentane tannate**, 60 mg.
NO. OF INGREDIENTS: 4
INDICATIONS: Cough **cold** with decongestnat, antihistamine, antitussive
DOSE FORM: film-coated tabs
PACKAGE/PRICE: film-coated tabs 100

=> D IALL 8

L17 ANSWER 8 OF 11 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 94:44391 DRUGLAUNCH
SOURCE: Drug Launches, (27 Apr 1992)
DOCUMENT NUMBER: 0044406
TRADE NAME: TANORAL
MANUFACTURER: Genetco
CORPORATION: Genetco
LAUNCH COUNTRY: United States
LAUNCH DATE: Dec 1991
CLASSIFICATION: R1B Systemic **Rhinologicals**
COMPOSITION: Active Ingredient: **phenylephrine tannate**, 25 mg; **chlorpheniramine tannate**, 8 mg; pyrilamine tannate, 25 mg

NO. OF INGREDIENTS: 3
INDICATIONS: Relief of **nasal** congestion due to **colds** and allergy
DOSE FORM: tabs
PACKAGE/PRICE: tabs 100

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L17 ANSWER 9 OF 11 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 94:41007 DRUGLAUNCH
SOURCE: Drug Launches, (29 Jul 1991)
DOCUMENT NUMBER: 0041022
TRADE NAME: HISTATUSS
MANUFACTURER: Luchem
CORPORATION: Luchem
LAUNCH COUNTRY: United States
LAUNCH DATE: Mar 1991
CLASSIFICATION: R5A Cold Preparations without Anti-infectives
COMPOSITION: Active Ingredient: per 5 ml: **phenylephrine tannate**, 5 mg; ephedrine tannate, 5 mg; **chlorpheniramine tannate**, 4 mg; **carbetapentane tannate**, 30 mg
NO. OF INGREDIENTS: 4
INDICATIONS: Cough **cold** preparation
DOSE FORM: ped susp
PACKAGE/PRICE: ped susp 480 ml

=> D IALL 10

L17 ANSWER 10 OF 11 DRUGLAUNCH COPYRIGHT 1999 IMSWORLD

ACCESSION NUMBER: 94:20267 DRUGLAUNCH
SOURCE: Drug Launches, (21 Sep 1987)
DOCUMENT NUMBER: 0020282
TRADE NAME: TRI-TANNATE
MANUFACTURER: Rugby
CORPORATION: Rugby Labs
LAUNCH COUNTRY: United States
LAUNCH DATE: Mar 1987
CLASSIFICATION: R1B Systemic **Rhinologicals**
COMPOSITION: Active Ingredient: **phenylephrine tannate**, 25 mg (tab)/5 mg (5 ml susp); **chlorpheniramine tannate**, 8 mg (tab)/2 mg (5 ml susp); pyrilamine tannate, 25 mg (tab)/12.5 mg (5 ml susp)
NO. OF INGREDIENTS: 3
INDICATIONS: For symptomatic relief of the **coryza** and **nasal** congestion
DOSE FORM: tabs
PACKAGE/PRICE: tabs 100 ped susp 16 oz

L2 ANSWER 9 OF 14 DRUGLAUNCH COPYRIGHT 2000 IMSWORLD

ACCESSION NUMBER: 94:20267 DRUGLAUNCH
SOURCE: Drug Launches, (21 Sep 1987)
DOCUMENT NUMBER: 1002267
TRADE NAME: TRI-TANNATE
MANUFACTURER: Rugby
CORPORATION: Rugby Labs
LAUNCH COUNTRY: United States
LAUNCH DATE: Mar 1987
CLASSIFICATION: R1B Systemic Rhinologicals
COMPOSITION: Active Ingredient: phenylephrine tannate, 25 mg (tab)/5 mg (5 ml susp); chlorpheniraminetannate, 8 mg (tab)/2 mg (5 ml susp); pyrilamine tannate, 25 mg (tab)/12.5 mg(5 ml susp).
NO. OF INGREDIENTS: 3
INDICATIONS: For symptomatic relief of the coryza and nasal congestion
DOSE FORM: tabs
PACKAGE/PRICE: tabs 100 ped susp 16 oz

ACCESSION NUMBER:	94:44391 DRUGLAUNCH
SOURCE:	Drug Launches, (27 Apr 1992)
DOCUMENT NUMBER:	1025217
TRADE NAME:	**TANORAL**
MANUFACTURER:	Genetco
CORPORATION:	Genetco
LAUNCH COUNTRY:	United States
LAUNCH DATE:	Dec 1991
CLASSIFICATION:	R1B Systemic Rhinologicals
COMPOSITION:	Active Ingredient: phenylephrine tannate, 25 mg; chlorpheniramine tannate, 8 mg; pyrilaminetannate, 25 mg.
NO. OF INGREDIENTS:	3
INDICATIONS:	Relief of nasal congestion due to colds and allergy
DOSE FORM:	tabs

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